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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/494,585	01/31/2000	Richard A. Shimkets	15966-557(Cura-57)	3648

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EXAMINER	
SAOUD, CHRISTINE J	
ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/494,585	SHIMKETS et al.
Examiner	**Art Unit**
Christine Saoud	1647

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Mar 17, 2003*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 2, 4, 5, 7-10, 14, 19-21, 28, and 29* is/are pending in the application.

4a) Of the above, claim(s) *21* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 2, 4, 5, 7-10, 14, 19, 20, 28, and 29* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 17 March 2003 has been entered.

Response to Amendment

2. Claims 1, 2, 4, 5, 14, 19, 20, 28 and 29 have been amended as requested in the amendment of paper #22, filed 17 March 2003. Claims 1-2, 4-5, 7-10, 14, 19-21 and 28-29 are pending in the instant application. Applicant requested that claim 21 be withdrawn from consideration as being directed to a non-elected invention (see page 2 of paper #15). Accordingly, claims 1-2, 4-5, 7-10, 14, 19-20 and 28-29 are under examination in the instant application. Claim 21 is still pending, but is withdrawn as requested by Applicant.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed 17 March 2003 have been fully considered but they are not deemed to be persuasive.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-2, 4-5, 7-10, 14, 19-20, 28-29 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility for the reasons of record in paper #12 and 17.

Applicant argues at page 4 of the response that "the specification makes a specific assertion of utility of the claimed invention" that the "proteins encoded by the novel nucleic acids of this invention may be used to stimulate cell growth, including especially growth of fibroblasts and epithelial cells in the linings of the gastrointestinal tract". However, this assertion is not supported by the specification as filed, in that the specification as originally filed did not indicate that the claimed invention should or could be used "especially" for the growth of cells of the GI tract. The instant specification asserts that the "FGF-CX" protein of the instant application could be used in a method of diagnosing a tissue proliferation-associated disorder, "such as tumors,

restenosis, psoriasis, diabetic and post-surgery complications, and rheumatoid arthritis" (see page 4, lines 26-28 of the specification), in a method of "treating or preventing or delaying a tissue proliferation-associated disorder" (page 5, lines 28-29 of the specification) by administration of a FGF-CX nucleic acid, polypeptide or antibody, wherein the disorder includes tumors, restenosis, psoriasis, Dupuytren's contracture, diabetic complications, Kaposi sarcoma, and rheumatoid arthritis (see page 6, lines 6-7 of the specification), in a method of treating or diagnosing glia-associated disorders, including "cerebral lesions, cerebral edema, senile dementia, Alzheimer's disease, diabetic neuropathies, etc." (see page 58, lines 2-4), stimulating fibroblasts, megakaryocytes, hematopoietic cells, immune system cells, vascular smooth muscle cells treating bone fractures and osteoporosis, diagnosis and treatment of cerebral tumors (see page 58, lines 11-16). The fact that the specification also includes a recitation that the claimed invention may also stimulate cells of the gastrointestinal tract in addition to all of the other possible uses of the claimed invention does not appear to provide a substantial utility for the claimed invention as filed. A substantial utility is a utility that defines a "real world use". Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. In the instant situation, the specification lists numerous uses for the claimed invention which are not linked by tissue type or mechanism of action; i.e. if the invention works for one of the asserted uses, then the skilled artisan would have a reasonable expectation that it would work for the other asserted uses. Therefore, the skilled artisan would need to carry out further research on the claimed invention to determine which of the possible

asserted uses the claimed invention could be used for; this does not constitute a disclosure of a substantial utility.

Applicant's submission of the Jeffers et al. reference is noted. The references to a Press Release regarding FDA approval of CuraGen's drug application is also noted. However, since the instant specification fails to disclose a specific, substantial and credible utility for the claimed invention at the time the application was filed, this evidence is not persuasive to overcome the rejection.

Applicant additionally argues at page 5 of the response that "utility is supported by the structural similarity of this FGF-20 with other known members of the FGF family". This argument is not persuasive and has been addressed previously. As illustrated by Galzie et al., the FGF family does not share the same specific, substantial and credible utility since they have distinct biological activities which cannot be predicted from their amino acid structure. Applicant asserts that the claimed protein has a biological activity similar to a structurally related protein (FGF-9), however, these two proteins do not have the same utility since FGF-9 stimulates glial cells and the claimed protein does not. The ability of an FGF protein to stimulate endothelial cells is not a specific utility because the FGF proteins are specific for particular endothelial cells. For example, KGF stimulates keratinocytes but not fibroblasts, therefore, it cannot be used in the same way as an FGF which stimulates fibroblasts. bFGF stimulates fibroblasts and FGF-9 stimulates glial cells, and therefore, they cannot be used for the same purpose. The members of the FGF family have divergent activities in that they typically stimulate particular cell types or act on particular tissues and they are not predictive of one another. Assignment to the FGF family is

not predictive of a utility of stimulating cells of the GI tract because this is but one tissue of endothelial cell origin for which the FGF proteins are known to stimulate and the skilled artisan would need to carry out further research on the claimed invention to identify or reasonably confirm which tissue the claimed invention would stimulate.

Applicant argues that a 132 Declaration was filed in support of utility. This Declaration (paper #14) was considered in paper #17 and not found to be persuasive.

Applicant additionally argues that a "how to use" rejection cannot stand because the instant situation does not meet the criterion of being totally incapable of achieving a useful result. This argument is not persuasive. Since the instant specification fails to provide a specific, substantial and credible utility for the claimed invention, the specification clearly does not teach how to use the claimed invention.

Claim Rejections - 35 USC § 112

8. Claims 1-2, 4-5, 7-10, 14, 19-20, 28-29 are rejected under 35 U.S.C. §112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. §101 and for the reasons of record in paper #12 and 17.

9. Claims 14 and 29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the

art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 14 is directed to a method of producing a polypeptide. However, claim 14 ultimately depends from claim 1, which includes both encoding and complementary nucleic acid molecules. The instant specification fails to teach how to make a polypeptide using the complementary nucleic acid molecule which by definition does not encode the polypeptide, therefore, the claim is not enabled for such material. Applicant argues that claim 14 recites that the FGF-CX polypeptide is defined by the amino acid sequence provided in SEQ ID NO:2. This argument is not persuasive because the method calls for the use of the host cell of claim 10 which contains the DNA of claim 1, which specifically recites coding and non-coding DNA. This rejection could easily be corrected by an intervening claim to the coding strand, or rewriting the method as an independent claim.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1, 3-4, 19-21, 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "encoding a polypeptide comprising a sequence of SEQ ID NO:2". This claim could be interpreted in a number of ways; (1) the polypeptide comprises the amino acid

sequence of SEQ ID NO:2 or (2) the polypeptide comprises some subsequence of SEQ ID NO:2 because of the recitation "a sequence of SEQ ID NO:2". Although the specification does not appear to support subsequences of SEQ ID NO:2, this is a possible interpretation of this recitation, and therefore, the claim is indefinite. It is suggested that the claim recite "a polypeptide comprising the amino acid sequence of SEQ ID NO:2", which would obviate this ground of rejection.

Claim 2 recites "encodes a polypeptide of SEQ ID NO:2". As with claim 1 above, the recitation of "a polypeptide of SEQ ID NO:2" implies that there may be more than 1 polypeptide encompassed by SEQ ID NO:2. A review of the specification does not appear to support multiple polypeptides originating from SEQ ID NO:2, but again, this is a possible interpretation of the claim. Therefore, the metes and bounds of what is being claimed cannot be determined. It is suggested that the claim recite "encodes the polypeptide of SEQ ID NO:2", which would obviate this ground of rejection.

Claims 4 and 28 recite "hybridizes .... under stringent conditions", wherein such conditions are not fully recited in the claim. It is appreciated that the claims now include those conditions with which the test DNA is to hybridize to the sample molecule, but those nucleic acids which are remain are determined by the wash conditions which are not recited in the claims. In other words, which nucleic acids are to be isolated depends on the wash conditions which are used following the hybridization procedure (which is also part of the hybridization conditions). In the absence of wash conditions, the metes and bounds of "hybridizing under stringent conditions" cannot be

determined because, depending on the conditions which are used, many different molecules could be intended by the claims.

Conclusion

12. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Christine J. Saoud, Ph.D., whose telephone number is (703) 305-7519. The Examiner can normally be reached on Monday to Thursday from 8AM to 2PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. §§ 1.6(d) and 1.8). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternate number. Official papers filed After Final rejection filed by fax should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud